

REMARKS

The Examiner has rejected independent claims 1, 21, and 22 as being anticipated by *Nadol*.¹ In doing so, the Examiner suggests that if the balloon were to transmit even the most miniscule of vibrations to the eardrum, it would satisfy the limitation of having an acoustic impedance low enough to permit the eardrum to respond, however imperceptibly, to an incident wave.

Nadol does not, however, include any teaching of how one would actually achieve this. In fact, *Nadol* itself concedes that

“[t]he amount of flexibility which is necessary for good compressive response of a membrane and the balloon is unknown and difficult to quantify.”²

Applicant's work renders the foregoing statement obsolete. Based on this work, it is no longer the case that the required flexibility is unknown and difficult to quantify. Applicant has identified a relationship between the equivalent volume of a balloon and the flexibility required to transmit vibrations with enough efficiency to restore hearing. No such relationship is suggested by *Nadol*.

In rejecting claim 2 only on the basis of double-patenting, the Examiner appears to agree that *Nadol* teaches no relationship between equivalent volume and the required flexibility. However, claim 2 recites a numerical limitation on the equivalent volume. Since *Nadol* does not teach a relationship between equivalent volume and required flexibility, the numerical limitation of claim 2 is in fact not needed to overcome the cited art. Accordingly, Applicant amends the independent claims to include a limitation of selecting an equivalent volume generally, without a numerical limitation.

Claims 1-22 also stand rejected on the basis of double-patenting. In response, Applicant submits a terminal disclaimer executed by the assignee.

¹ *Nadol*, U.S. Patent No. 5,536,430.

² *Nadol*, col. 4, lines 11-13.

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Now pending in this application are claims 1-26, of which claims 1, 21, and 22 are independent. Attached is a marked-up version of the changes being made by the current amendment. Enclosed is a check for the extension fee. No additional fees are believed to be due in connection with the filing of this response. However, to the extent fees are due, or if a refund is forthcoming, please adjust our deposit account 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

Claims 1, 2, 21, and 22 have been amended as follows:

1. (Amended) An implant for implantation in a middle-ear chamber, said implant comprising:

a pliant membrane formed into a balloon, said balloon configured to fit within said middle-ear chamber and to contact an eardrum, said pliant membrane ~~[being selected to]~~ forming a balloon having an equivalent volume selected ~~[acoustic impedance low enough]~~ to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound.

2. (Amended) The implant of claim 1, wherein said pliant membrane forms a balloon having an acoustic impedance corresponding to an equivalent volume of at least 70% of its physical volume.

21. (Amended) An implant for implantation in a middle-ear chamber, said implant comprising:

a plurality of balloons formed from a pliant membrane, said balloons configured to fit within said middle-ear chamber with at least one of said balloons at least partially in contact with the eardrum, each of said balloons having an equivalent volume selected ~~[acoustic impedance low enough]~~ to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound.

22. (Amended) A surgical method for treating middle-ear hearing loss of a patient, said method comprising:

positioning a balloon in the patient's middle ear at least partially in contact with the eardrum, said synthetic balloon being formed of a thin pliant membrane of biocompatible material such that said balloon has an equivalent volume high [~~impedance low~~] enough to permit sound-induced motions of the eardrum, ossicles, and the round window membrane to an extent that permits the perception of sound by said patient, said pliant membrane being substantially impermeable to water and to gases during extended contact with body tissues.